



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,024	12/11/2003	David B. Weiner	UPVG0005-101	2356
34132	7590	10/31/2006	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,024

Applicant(s)

WEINER ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 14-18, 20-23, 25-27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 14-18, 20-23, 25-27 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is in response to the amendment filed on 23 August 2006. Claims 6-13, 19, 24, and 28 have been cancelled. Claims 29-34 have been added. Claims 1-5, 14-18, 20-23, 25-27, and 29-34 are pending and under final rejection.

Claim Rejections - 35 USC § 112

The rejection of claims 1-5 and 14-28 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope is **partially withdrawn for claims 16-18 and 21-23** in view of the amendment and **partially maintained for claims 1-5, 14, 15, 20, and 25-27, and extended to new claims 29-34**. Applicants' arguments have been fully considered but are not persuasive. Applicants argue that those skilled in the art viewing Rogel would not conclude that all fragments of Vpr would not have the inhibition of cell proliferation function and that disclosure of a single non-functioning fragment would not lead them to conclude that all fragments of Vpr are non-functioning. While agreeing with the Applicants, Examiner would like to point out that the citation of Rogel *et al.* is only one factor, level of skill and knowledge in the art, in considering whether Applicants have possession of a genus of functional fragments of Vpr. The most important factor that has not been met by the instant disclosure is the partial structure of the claimed fragment that correlates with function. Therefore, in view of the complete analysis of the factors set forth in MPEP § 2163 and absent representative species that reflect the

Art Unit: 1648

claimed genus, Applicants do not have possession of the genus of functional Vpr fragments.

Claim Rejections - 35 USC § 102

The rejection of claims 6-13, 19, 24, 28 under 35 U.S.C. §102(a) as being anticipated by Rogel *et al.* (February, 1995, filed in IDS) is **withdrawn** in view of the claim cancellation.

The rejection of claims 1-5, 14-18, 20-23, and 25-27 under 35 U.S.C. §102(a) as being anticipated by Rogel *et al.* (February, 1995, filed in IDS) is **withdrawn** in view of the amendment.

Claim Rejections - 35 USC § 103

Claims 1-5, 14-18, 20-23, 25-27, and 29-34 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rogel *et al.* (February, 1995).

The instant invention is a method of inhibiting proliferation of cells which comprises the steps of: obtaining isolated Vpr protein or a functional fragment thereof; and contacting cells with an amount of said Vpr protein or a functional fragment thereof effective to inhibit cell proliferation.

Rogel *et al.* teach that transfection of two T lymphocyte cell lines, Sup T1 and MT4 cells, with viral strains containing Vpr protein, prevents T cell proliferation or activation (pages 883-884, Figure 1). Rogel *et al.* do not explicitly teach obtaining an isolated Vpr protein or a functional fragment thereof and contacting cells with Vpr

Art Unit: 1648

protein. However, Rogel *et al.* emphatically teach that Vpr expression can alter the progression of cells in the cell cycle and therefore may mediate its effect through prevention of cell proliferation (page 882, right column, first ¶). A plasmid or virus containing a *vpr* gene is simply a delivery vehicle to ensure the presence of Vpr protein inside the cells.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the *vpr*-containing plasmid or nucleotide of Rogel *et al.* with isolated Vpr protein. The skilled artisan would have been motivated to do so to speed up the process by eliminating the preliminary step of Vpr expression inside the cells. There would have been a reasonable expectation of success, given that the prevention of cell proliferation is mediated by Vpr protein activity rather than the *vpr* gene, as taught by Rogel *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1648

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Jeffrey Parkin, Ph.D.
Primary Examiner
18 October 2006


10/17/2006